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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,697	01/04/2007	Veit Krenn	BB-170	6576

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EXAMINER	
HARRIS, ALANA M	
ART UNIT	**PAPER NUMBER**
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,697	KRENN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/20/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *10-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 15* is/are rejected.

7)☒ Claim(s) *4-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-9 and 15) in the reply filed on November 28, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

2. Claims 4-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only; and/or; and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

3. Claim 15 is objected to because of the following informality: it depends on a non-elected claim, claim 14. Correction is required.

4. Claims 1-15 are pending.

Claims 10-14, drawn to non-elected inventions are withdrawn from examination.

Claims 4-9, drawn to multiple dependent claims are not further treated on the merits.

Claims 1-3 and 15 are examined on the merits, with the election of species, CDw52.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3 provide for the use of a ligand of a cellular marker, CDw52, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well

established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0191328 A1 (effective filing date December 31, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005). Applicants are reminded the claimed invention elected solely reads on

a method of making a medicament comprising a ligand of CDw52 and dependent claims read on inherent features of the antigen the ligand binds. The publication discloses a method of preparing a medicament comprising alemtuzumab also art known as Campath® in combination with chemotherapeutic agent, gallium nitrate for the treatment of neoplasms, see abstract; section 0010 bridging pages 1 and 2; section 0031 bridging pages 3 and 4; page 3, section 0025; and page 4, sections 0036 and 0037. Guenther evidences it is art known cellular marker CDw52 is expressed on bone tumors, giant cell tumors and osteosarcomas, see page 656, Immunohistochemical...section, 2nd paragraph; and page 660, 2nd column, 1st full paragraph.

11. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 7,105,682 B2 (filed January 10, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005). Applicants are reminded the claimed invention elected solely reads on a method of making a medicament comprising a ligand of CDw52 and dependent claims read on inherent features of the antigen the ligand binds. The patent discloses a method of making pharmaceutical composition comprising alemtuzumab in combination with chemotherapy for the treatment of neoplasms, such as bone cancers and osteosarcomas, see abstract; column 36, lines 9-29; column 46, lines 1-17; and column 48, lines 26-28. This disclosure, as well as Guenther evidences it is art known cellular marker CDw52 is expressed on bone tumors, giant cell tumors and osteosarcomas, see page 656,

Immunohistochemical...section, 2nd paragraph; and page 660, 2nd column, 1st full paragraph.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2004/0191328 A1 (effective filing date December 31, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005/ IDS reference F1 submitted November 27, 2006), and further in view of WO 03/050257 A2 (published June 19, 2003). The teachings and evidence of the publication and Guenther, respectively have been presented in the first cited 102(e) rejection. The publication does not teach the disclosed method, wherein ligands of CDw52 antigen were screened comprising incubating a cell expressing CDw52, measuring binding between the said antigen.

However, WO 03/050257 teaches microarray analysis and targeting a molecule to a cell. The method includes the steps of: first contacting the cell with a retinoid in an amount effective to increase the expression of a marker in the cell; and second contacting the cell with an agent that specifically binds the marker, such as a substance that specifically binds the marker, an anti-CD52 antibody, page 3. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention

was made to screen for ligands that bind the CDw52 antigen in order to identify products potentially useful in methods of cancer immunotherapy. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the recited documents because these identified ligands could be presented as a pharmaceutical product to implement targeted treatments in cancer.

14. Claims 1-3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,105,682 B2 (filed January 10, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005), and further in view of WO 03/050257 A2 (published June 19, 2003/ IDS reference F1 submitted November 27, 2006). The teachings and evidence of the publication and Guenther, respectively have been presented in the second cited 102(e) rejection. The patent does not teach the disclosed method, wherein ligands of CDw52 antigen were screened comprising incubating a cell expressing CDw52, measuring binding between the said antigen.

However, WO 03/050257 teaches microarray analysis and targeting a molecule to a cell. The method includes the steps of: first contacting the cell with a retinoid in an amount effective to increase the expression of a marker in the cell; and second contacting the cell with an agent that specifically binds the marker, such as a substance that specifically binds the marker, an anti-CD52 antibody, page 3. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to screen for ligands that bind the CDw52 antigen in order to identify products potentially useful in methods of cancer immunotherapy. One of ordinary skill

in the art would have been motivated to do so with a reasonable expectation of success by teachings in the recited documents because these identified ligands could be presented as a pharmaceutical product to implement targeted treatments in cancer.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
01 February 2008